

### **REMARKS**

Claims 1 through 17, 19 through 36 and 38 are pending in the application. Claims 18 and 37 have been canceled by this amendment.

Claims 1 through 3, 18, 20 through 22 and 37 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Swanson (5,783,502).

Swanson describes compositions and methods for modifying medical fabrics in order to inactivate viruses upon contact. The compositions include photochemically immobilizing hydrophilic polymers having both quaternary ammonium groups and hydrocarbon chains. The medical fabrics include those used to prepare surgical gloves, drapes, masks and dressings.

Independent claim 1 recites a tampon having an absorbent material and a composition disposed in the absorbent material. The composition has at least one antibacterial agent and at least one finishing agent, wherein the composition has synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin and reduce *Staphylococcus aureus* bacteria growth.

Independent claim 20 recites a method of inhibiting the production of TSST-1 toxin by exposing TSST-1 toxin-producing *Staphylococcus aureus* bacteria to a tampon, with the tampon having an absorbent material and a composition. The composition has at least one antibacterial agent and at least one finishing agent, wherein the composition has synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin and reduce *Staphylococcus aureus* bacteria growth.

Applicants respectfully maintain that Swanson fails to disclose or suggest a tampon having a composition with synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin and reduce *Staphylococcus aureus* bacteria growth, as recited in claims 1 and 20. There is absolutely no disclosure or suggestion in Swanson that their polymeric coating composition is remotely capable of both TSST-1 toxin neutralization and reducing *Staphylococcus aureus* bacteria growth. Therefore, Swanson cannot anticipate the claimed invention.

Moreover, Applicants again respectfully disagree with the Action's contention that Swanson's polymeric coating composition having antiviral groups used to inactivate viruses is inherently capable of synergistically neutralizing the production of TSST-1 toxin and reducing *Staphylococcus aureus* bacteria growth, as recited in claims 1 and 20 of the present application.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)(citations omitted).

It is respectfully reiterated that the Action clearly fails to cite any rationale or extrinsic evidence found in Swanson, or anywhere else, that makes clear that Swanson's polymeric coating composition possesses the synergistic TSST-1 toxin neutralization and *Staphylococcus aureus* antibacterial properties unexpectedly found with the presently claimed composition. Therefore, the Action impermissibly relies on a mere possibility that the claimed properties are capable in the cited prior

art. Absent any extrinsic evidence making clear that the claimed properties are necessarily present in Swanson, the Action cannot and does not establish inherency. It is only through the present application that a tampon with such a composition having synergistic neutralization and antibacterial properties is disclosed or suggested. Therefore, the tampon recited in claims 1 and 20, is clearly not anticipated by the cited art.

As such, it is respectfully submitted that claims 1 and 20, as well as claims 2 and 3, which depend from claim 1, and claims 21 and 22, which depend from independent claim 20, are patentably distinguishable over Swanson for at least the reasons set forth above. Reconsideration and withdrawal of the §102(b) rejection of these claims are respectfully requested.

Claims 4 through 14, 17, 19, 23 through 32, 35, 36 and 38 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Swanson (5,783,502) in view of Merritt (6,245,361).

Swanson is summarized above. Merritt describes an aqueous cleaning and disinfecting composition having a chlorine-containing bleach compound and a bactericidal quaternary ammonium compound. The composition is used in cleaning and disinfecting hard surfaces, such as, countertops, work areas, rest rooms, meat packing rooms, food handling areas and the like (col. 8, lines 48 and 49). Notably, Merritt is particularly concerned with tubercule bacilli found on hard surfaces.

Applicants respectfully submit that Merritt is directed to non-analogous art, and therefore, cannot be relied on as a basis for rejection of the present claims. "In order to rely on a reference as a basis for rejection of applicant's invention, the reference must either be in the field of the applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was

concerned." *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

It is clear that the claimed invention, directed to a tampon having a composition with synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin and reduce *Staphylococcus aureus* bacteria growth, is not in the same field of endeavor as Merritt, namely hard surface disinfectant cleaners. There is absolutely no indication in Merritt that would have commended itself to the attention of one skilled in the art concerned with tampons, let alone tampons associated with TSST-1 toxin and/or *Staphylococcus aureus* bacteria, as claimed. To the contrary, one skilled in the art would not look to a reference that teaches a bleach-containing hard surface cleaner, since one would not put bleach on a tampon intended for insertion into a woman's vagina, for health and safety concerns alone.

The Action maintains that Swanson and Merritt can be combined due to the fact that "...the examiner is only relying on the Merritt reference for the use of the antibacterial, quaternary ammonium compound, which Merritt states is a good antibacterial agent for the use in medical field. The examiner is not replacing the entire compound of Swanson with the compound of Merritt, the examiner is only taking the antibacterial compound from Merritt. The part of the compound that makes it for use in an industrial situation is the use of bleach, however the bleach is not relied upon or being used in the combination of references." The examiner concludes from this reasoning that motivation exists to combine the teachings of Swanson with Merritt.

First, Applicants respectfully disagree with the Action's characterization of Merritt, as quoted above. Particularly, Applicants are unable to find support for the contention "...quaternary ammonium compound, which Merritt states is a good antibacterial agent for use in the medical field." In fact, Merritt generally discloses

that quaternary ammonium compounds are recognized as being useful for their antibacterial properties (col. 2, lines 24-26), and in the case of Merritt are useful for cleaning hard surfaces when combined in a specific amount with a specific amount of chlorine.

Second, to make a *prima facie* case of obviousness under §103, there must be motivation in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine reference teachings. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

As is clear, Swanson fails to disclose or suggest a tampon with a composition having the claimed synergistic neutralization and antibacterial properties. Since Swanson is devoid of any suggestion that TSST-1 toxin and/or *Staphylococcus aureus* bacteria are even a concern with tampons, it follows that there exists no motivation to one skilled in the art to look to any other reference to fill the void in Swanson. It is only through impermissible hindsight reconstruction that one would find any motivation to look elsewhere to modify the teachings of Swanson to arrive at the claimed invention.

Moreover, even if one incorrectly looked to Merritt, the deficiencies of Swanson would not be satisfied, namely because Merritt also fails to remotely disclose or suggest a tampon, let alone one having the claimed synergistic neutralization and antibacterial properties.

As such, Applicants respectfully submit that claims 4 through 14, 17, 19, 23 through 32, 35, 36, and 38, all of which depend from either claim 1 or claim 20, are patentably distinguishable over the cited combination of references. Reconsideration and withdrawal of the §103(a) rejection of these claims are respectfully requested.

Claims 15, 16, 33 and 34 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Swanson and Merritt as applied to claims 1, 13, 14, 20, 31 and 32 above, and further in view of Hama et al. (5,817,844).

Hama is directed to a method of manufacturing a fatty acid ester of polyoxyalkylene alkyl ether in which a fatty acid ester of polyoxyalkylene alkyl ether of a specific formula is produced.

Claim 15 depends indirectly from independent claim 1 and adds that the at least one finishing agent be one or more nonionic surfactants, and that the one or more nonionic surfactants is one or more polyoxyethylene fatty acid esters.

Claim 16 depends indirectly from claim 15, and adds that of the polyoxyethylene fatty acid ester be present in an amount about 2.5 wt.% based on the total weight of the tampon.

Claims 33 and 34 depend indirectly from claim 20, and recite similar features as those recited in claims 15 and 16.

Applicants respectfully submit that, as discussed above with respect to claims 1 and 20, Swanson and Merritt clearly fail to disclose or suggest, alone or in combination, a tampon with a composition having a synergistic combination of at least one antibacterial agent and at least one finishing agent effective to neutralize the production of TSST-1 toxin and reduce *Staphylococcus aureus* bacteria growth, as claimed. Hama fails to cure this deficiency, as Hama fails to disclose or suggest any tampon, let alone a tampon with a composition having a synergistic combination of at least one antibacterial agent and at least one finishing agent effective to neutralize the production of TSST-1 toxin and reduce *Staphylococcus aureus* bacteria growth.

Moreover, with respect to claim 16, Swanson and Merritt fail to disclose or suggest the claimed amount of polyoxyethylene fatty acid ester based on the total weight of the tampon. Hama has no disclosure or suggestion of the amount of polyoxyethylene fatty acid ester present, let alone present based on the total weight of the tampon and therefore, does not cure the deficiencies of Swanson and Merritt.

Therefore, Applicants respectfully submit that claims 15 and 16 are patentably distinguishable over the cited art and the cited combination thereof. Furthermore, claims 33 and 34, which depend directly or indirectly from independent claim 20 and recite similar features as claims 15 and 16, are patentably distinguishable for at least the reasons discussed above with respect to claims 15, 16 and 20.

In view of the foregoing, Applicants respectfully submit that all claims presented in this application are patentably distinguishable over the cited prior art, taken alone or in combination. Accordingly, Applicants respectfully request favorable consideration and the passage of all claims to allowance.

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Respectfully submitted,

A handwritten signature in black ink, appearing to read "Charles N.J. Ruggiero", is written over a horizontal line.

Charles N.J. Ruggiero

Attorney for Applicants

Reg. No. 28,468

Ohlandt, Greeley, Ruggiero & Perle, L.L.P.

One Landmark Square, 10<sup>th</sup> Floor

Stamford CT 06901-2682

Tel: 203-327-4500

Fax: 203-327-6401